

REMARKS

New claims 20 and 21 have been added. Support for claims 20 and 21 is found on page 22, Example 8, of the specification as filed. Claims 11 and 19 have been amended to delete the phrase “the DNA content of the liver basement membrane is about 0.566 to about 0.04 micrograms of DNA per milligram of dry weight of the liver basement membrane.” Additionally, claims 11 and 19 have been amended to add the phrase “the purified liver basement membrane is substantially devoid of DNA.” Support for this amendment can be found, for example, on page 23, lines 1-3, of the specification as filed, and on page 22, Example 8.

35 U.S.C. § 112, paragraph 1-

Claims 11-15, and 17-19 stand rejected under 35 U.S.C. § 112, paragraph 1, as failing to comply with the written description requirement. The Examiner contends that the phrase “the DNA content of the liver basement membrane is about 0.566 to about 0.04 micrograms of DNA per milligram of dry weight of the liver basement membrane” in the claims constitutes new matter. Applicants have amended claims 11 and 19 to remove the phrase “the DNA content of the liver basement membrane is about 0.566 to about 0.04 micrograms of DNA per milligram of dry weight of the liver basement membrane.” Accordingly, the Examiner’s rejection under 35 U.S.C. § 112, paragraph 1, has been rendered moot. Withdrawal of the rejection of claims 11-15 and 17-19 under 35 U.S.C. § 112, paragraph 1, is respectfully requested.

35 U.S.C. §§ 102(e) and 102(b)-

The Examiner has rejected claims 11-15 and 17-19 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,379,710 (the ‘710 patent) and under 35 U.S.C. § 102(b) as

being anticipated by WO 98/25637. Additionally, the Examiner has rejected claim 19 under 35 U.S.C. § 102(b) as being anticipated by Brendel et al. (*Advances in Experimental Medicine and Biology*, 1980, 131: 89-103) and Robinson et al. (*European Journal of Biochemistry/FEBS*, 1980, 111: 485-490). The '710 patent issued from the U.S. National Application based on PCT/US97/22727 (Publication No. WO 98/25637). Thus, the arguments below will apply with equal force to both of these Badylak references cited by the Examiner.

The Examiner argues that it is inherent that the liver basement membrane as described in the '710 patent and WO 98/25637 has the DNA content recited in claims 11-15 and 17-19 of the present application. The Examiner further contends that it is inherent that the basement membrane compositions taught by Robinson et al. and Brendel et al. have the DNA content that is specified in Applicants' claim 19. Applicants respectfully traverse the Examiner's rejections. The '710 patent, WO 98/25637, Robinson et al., and Brendel et al. do not anticipate amended claims 11-15 and 17-19.

Anticipation exists only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). None of the '710 patent, WO 98/25637, Robinson et al., and Brendel et al. describes the same method of preparation of basement membrane compositions as described in the present application. Moreover, none of the '710 patent, WO 98/25637, Robinson et al., and Brendel et al. mentions DNA content. Thus, the Examiner has provided no evidence that it is inherent that the basement membrane compositions taught by the cited references are "substantially devoid of DNA" as specified in Applicants' amended claims 11 and 19, and their dependent claims.

Applicants' draw the Examiner's attention to MPEP § 2112, Part IV which describes the requirements for an Examiner to show inherency. MPEP § 2112, Part IV states that

The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

MPEP § 2112, Part IV. The Examiner has provided no evidence that any of the prior art references necessarily describes a basement membrane composition that is “substantially devoid of DNA” as claimed in amended claims 11 and 19. Again, as stated in MPEP § 2112, Part IV, inherency “may not be established by probabilities or possibilities” and “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.”

Different methods of preparation were used to make the prior art basement membrane compositions than were used to prepare Applicants’ compositions. Moreover, DNA content is not mentioned in the prior art references and no assays for the determination of DNA content were described in the prior art references. Consequently, the Examiner has not met her burden of demonstrating that the prior art references inherently describe compositions that are “substantially devoid of DNA” as claimed in Applicants’ amended claims. Thus, the ‘710 patent, WO 98/25637, Robinson et al., and Brendel et al. cannot be found to anticipate the amended claims of the instant application based on inherency. Withdrawal of the rejections of amended claims 11-15 and 17-19 under 35 U.S.C. §§ 102(e) and 102(b) is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. The claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,

A handwritten signature in black ink that reads "Rebecca Ball". The signature is written in a cursive, flowing style.

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